JAN 13 2006

K053362

510(k) Summary of Safety and Effectiveness

510(k) Submitter: Streck
7002 South 109th Street
Omaha, NE 68128

Official Correspondent: Carol Thompson, Quality Assurance Manager
(402)-537-5213

Date Prepared: December 1, 2005

Name of Device:
Trade Name: Cell-Chex Auto
Common Name: Hematology Control for Body Fluids
Classification Name: White and Red Blood Cell Control (864.8625)

Predicate Device: iQ® Body Fluids Control (K051706) Manufactured by Streck

Description:
Cell-Chex Auto is a stabilized suspension of human red blood cells and simulated white blood cells in a solution containing biological salts and anti-microbial preservatives. The product is packaged in plastic vials containing 4ml. The closures are polypropylene screw caps with polyethylene liners. There are three different levels, Level 1 with a very low count, Level with a low count, and a Level 3 with a higher count. The vials will be packaged in a six (6) or twelve (12) welled vacuum formed "clam-shell" container with the package insert / assay sheet. The product must be stored at 2 - 10°C.

Intended Use:
Cell-Chex Auto is an assayed whole blood control for evaluating the accuracy and precision of hematology instruments that measure blood cell counts in patient body fluid samples.

Comparison to Predicate Device:
Like iQ Body Fluids Control, Cell-Chex Auto is an assayed control mixture of red and white blood cells set at specific concentrations. iQ Body Fluids Control and Cell-Chex Auto have a 30 day open vial stability. Both iQ Body Fluids Control and Cell-Chex Auto are automated body fluid controls.

Unlike iQ Body Fluids Control, Cell-Chex Auto has 75 days closed vial stability where iQ Body Fluids Control has 159 days closed vial stability

Discussion of Tests and Test Results:
Four types of studies were conducted to establish performance of Cell-Chex Auto. The four tests conducted were Closed Vial Stability, Open Vial Stability, Run to Run Reproducibility, and Site to Site recovery of values. All testing showed that Cell-Chex Auto is consistently reproducible, substantially equivalent to the predicate product and stable for the shelf life claimed.

Conclusions Drawn From Tests:
Cell-Chex Auto is an effective quality control material for controlling hematology instruments that measure blood cell counts in body fluid samples when used as indicated on the labeling. It meets the claim of a 75 day closed vial, and a 30 day open vial stability and consistent run-to-run performance. Reproducibility studies and Closed Vial stability results confirm lot-to-lot consistency in the manufacture of Cell-Chex Auto. Customers can be assured of a reliable quality control material that meets their expectations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kerrie Oetter
Quality Assurance Coordinator
Streck Laboratories, Inc.
7002 South 109th Street
La Vista, NE 68128

JAN 13 2006

Re: k053362
Trade/Device Name: Cell-Chex Auto
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: Class II
Product Code: JPK
Dated: December 1, 2005
Received: December 2, 2005

Dear Ms. Oetter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K053362

Device Name: Cell-Chex Auto

Indications For Use:

Cell-Chex Auto is an assayed whole blood control for evaluating the accuracy and precision of hematology instruments that measure blood cell counts in patient body fluid samples.

Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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